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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/827,117 | 04/05/2001 | Ralph Williams | UF164D2 | 4924 |

29847 7590 06/13/2003

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EXAMINER

NOLAN, PATRICK J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 06/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/827,117

Applicant(s)
Williams

Examiner
Patrick J. Nolan

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 31, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, and 7 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, and 7 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Part III DETAILED ACTION

1. Claims 1-3 and 6-7 are pending.
2. Applicant is requested to update the first page of the specification to properly reflect the continuity data to 09/164,241 and 08/764,679.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2 and 6-7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an treating SLE with an antibody composition comprising anti-idiotypic antibodies specific for idiotypes F4, 3I, 8.12 and 16/5 does not reasonably provide enablement for treatment of all autoimmune disease with anti-idiotypic antibodies specific for idiotypes F4, 3I, 8.12 and 16/6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicant's invention is drawn to a method of treating with a composition of antibodies which specifically bind all the idiotypes F4, 3I, 8.12 and 16/6 found in anti-DNA antibodies in the autoimmune disease SLE. There is no recognition in the art that all of the idiotypes, F4, 3I, 8.12 and 16/6 exist in all autoimmune diseases. How could one of skill make and use Applicant's claimed invention when it is not recognized that all the idiotypes F4, 3I, 8.12 and 16/6 exist in all autoimmune diseases? Applicant's specification provides no working examples demonstrating that all the idiotypes exist in all autoimmune diseases, nor is there any guidance in the specification that all the idiotypes exist in all autoimmune diseases. The state of the art, the Merck Manual of Diagnosis and Therapy (U₁) does not even recognize that anti-DNA antibodies are present in most autoimmune diseases, see Table IV in particular. Since the invention is drawn to a method of treating all autoimmune diseases with a composition of antibodies which bind all four idiotypes found on anti-DNA antibodies found predominantly in SLE, and the prior art does not recognize, nor does the specification provide any working examples or guidance demonstrating that all of four idiotypes, F4, 3I, 8.12 and 16/6 are present in autoantibodies found in any other autoimmune disease, it would be unpredictable and require an undue amount of

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experimentation to make and practice the full breadth of Applicant's claimed invention.

5. Applicant is notified that claim 3 is objected as being dependent upon a rejected claim.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939.



Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
June 12, 2003